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08/574,461 11/30/95 BARONE

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EXAMINER

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ART UNIT PAPER NUMBER

1618

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | |
|------------------------------|--|--------------------------------------|
| Office Action Summary | Application No. 08/574,461 | Applicant(s) Barone et al. |
| | Examiner Joseph W. Ricigliano Ph. D. | Group Art Unit 1618 |

Responsive to communication(s) filed on Sep 20, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-8, 10-15, and 37-39 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-8, 10-15, and 37-39 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. This action is responsive to the amendment of 9/20/99. Claims 2 and 15 have been amended. Claims 1-8, 10-15, 37-39 are pending.

Claim Rejections - 35 USC § 112

2. Claim 39 and its dependent claims 2-7 and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have submitted new claim 39 which recites that the polymers comprise a label other than a monomer unit of the polymer. Applicants can over come this rejection by indicating where support for the limitation in claim 39 can be found in the application as originally submitted.

3. *Applicants' arguments filed 9/20/99 have been fully considered but they are not persuasive. Applicants argue that the recitation in question is supported at page 4 line 29 and page 29 line 19. This argument is not found persuasive because the recitation on page 4 at line 9 teaches that the methods of the instant invention are typically performed using a detectable monomeric mono-isomeric polymer synthesis reagent with the structure A-B where A comprises a detectable label and B is a polymer integration element. The same passage continues on to teach that the integration element B permits the joining of the label onto the end of the polymer or the incorporation of label A into the polymer. In either case it dose not support a label which is other than a monomeric unit of the polymer. The passage at page 25 is similarly in its teaching and is unpersuasive for the same reasons. Therefore, the rejection is maintained for the reasons above and for the reasons of record in paper number 23.*

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4. Claims 1-8, 10-15, 37-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The two independent claims have been amended to recite measuring a property of the mixture as an indicator of the efficiency of the synthesizing step. Applicants have indicated that support for amendment can be found on page 18 of the specification. However, the specification does not appear to support measuring a property of a mixture, rather, it appears to support measuring the presence of individual components present in the mixture via a property of the components. Applicants can over come this rejection by indicating where support for the limitation in claims 1 and 10 can be found in the application as originally submitted by page and line number.

5. *Applicants' arguments filed 9/20/99 have been fully considered but they are not persuasive.*

Applicants argue that measuring the presence of individual components in the mixture via a property of the components is in effect measuring a property of the mixture. This argument is not found persuasive because it fails to indicate where in the disclosure as originally filed the applicants have support for measuring the properties of the mixture rather than measuring the presence (concentration) of the components. As measuring the properties encompasses more than measuring the presence of the components (e.g., colligative properties or trubidimetric properties conductivity etc.), the rejection is maintained for the reasons above and for the reasons of record in paper number 23.

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6. Claims 1-8, 10-15, 37-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for measuring the presence of the individual components present in a mixture using a property of a label (i.e., the composition of the mixture) does not reasonably provide enablement for measuring a property of the mixture of diverse unbound polymers as an indicator of the efficiency of the synthesizing step. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 1-8, 10-15, 37-39 are directed toward a method of measuring polymer array synthesis. The disclosure teaches the synthesis and addition of a label to each member of a polymer array, subsequent cleavage of the array and analysis of the resulting mixture of polymers wherein the individual members of the array are detected by a property of the label added. However, the measurement of a property of the mixture itself as a measure of synthesis step efficiency does not appear to be within the scope of reasonable experimentation. The factors to be considered in a determination of undue experimentation are disclosed in *In re Wands*, (U.S.P.Q. 2d 1400 (CAFC 1988). The factors to be considered include: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the predictability of the art and the breadth of the claims.

Contrary to applicants assertions on page 5 of the 9/28/98 response the specification at page 18 does not support such methods and a number of factors would prevent one of skill in the

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art from practicing the invention without undue experimentation, these are summarized as follows:

- 1) The specification fails to give adequate direction and guidance to which properties of the mixture as a whole would be useful as a measure of synthetic efficiency.
- 2) Applicants have failed to provide any working examples where a property of the mixture as a whole is used to determine synthetic efficiency.
- 3) The breadth of the claims encompasses a large number of potential properties from vapor pressure measurements to conductivity.
- 4) The state of the prior art is such that the efficiency of array synthesis has been monitored by monitoring the composition of the population released from the supports (see 103 (a) rejection over Lam et al) not a property of the mixture itself
- 5) The art is inherently unpredictable because it is unclear how individual members will contribute to the bulk properties of the mixture. For example, an individual member of a population may strongly influence the conductivity of the mixture in a manner which is disproportionate to the efficiency of monomer incorporation.

Therefore, while it is true that the level of skill in the art is high, it would require undue experimentation to make and use the invention commensurate in scope with that claimed in the absence of explicit guidance as to which properties of the mixture are useful as indicators of synthetic efficiency and how to interpret them as set forth above.

7. *Applicants' arguments filed 9/20/99 have been fully considered but they are not persuasive.*

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Applicants' submit that measuring the presence of individual components is the mixture via a property of the components is in effect measuring a property of the mixture. This argument is not found persuasive because applicants' arguments are not commensurate in scope with the claimed subject matter. While measuring the presence of components present in the mixture may represent a single enabled embodiment of the claimed subject matter, it is not commensurate with measuring a property of the mixture. For example, a mixture in solution has numerous properties such as turbidity, electrical conductivity or colligative properties such as the freezing and boiling points which are not enabled by applicants for the instant methods. Moreover, it is unclear how different types of polymers (different backbones), which applicants argue may be present, will affect the properties of the mixture when they are present together. Therefore, the rejection is maintained for the reasons above and for the reasons of record in paper number 23.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-7, 10, 12-15, 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 3 -5 recite the polymer are heterogenous by size. This is vague and indefinite because it is unclear what "size" is meant to refer to. Does applicant intend size to be the number of monomeric units in the polymer, the mass, a measurement of length in some dimension or a measurement of volume? Therefore, it is not possible to determine the metes and bounds of the

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invention as claimed.

11. *Applicant's arguments filed 9/20/99 have been fully considered but they are not persuasive. Applicants argue that size is sufficiently clear and can refer to either a list of properties including the number of monomeric units, mass... This argument is not found persuasive as the claims are not limited to these properties. Applicants can overcome this rejection by amending the claims to recite the specific properties. Applicants are reminded to indicate where support can be found for such amendment in the disclosure as originally filed.*

12. Claim 39 and its dependent claims 2-7 and 37 recite that the polymers comprise a label other than the monomer unit of the polymers. This is vague and indefinite because is unclear how to interpret labels that form when a polymer is formed from monomer subunits when the monomers themselves do not contain the “label” per se (e.g., the “backbone” of the polymer becomes a chromophore itself). Moreover, it is unclear if this claim language is intended to exclude labels where only a portion of the monomer unit, (e.g., the indole of tryptophan) is a UV and fluorescent label but does not constitute a monomer of a peptide in and of itself. Therefore, it is not possible to determine the metes and bounds of the invention as claimed.

13. *Applicants' arguments filed 9/20/99 have been fully considered but they are not persuasive.*

Applicants argue that the claims are definite as the only thing required is that the label is different from the monomeric unit of the polymer. Applicants also refer to specific passages including those on pages 3, 4 and 25-29. These arguments have been considered but are not persuasive as they do not address the issue of how to interpret what is a label as previously

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recited. Moreover, the recitation on page 4 at line 9 teaches that the methods of the instant invention are typically performed using a detectable monomeric mono-isomeric polymer synthesis reagent with the structure A-B where A comprises a detectable label and B is a polymer integration element. The same passage continues on to teach that the integration element permits the joining of the label onto the end of the polymer or the incorporation of label A into the polymer. In either case it the label is a group attached to something that can be part of the polymer and even incorporated into the polymer. As such, it is not readily distinguishable from the polymer itself. By this standard the amino acid tryptophan would constitute a label as well as a monomer of a peptide. The passage at page 25 is similarly in its teaching and is unpersuasive for the same reasons. Therefore, the rejection is maintained for the reasons above and for the reasons of record in paper number 23.

Claim Rejections - 35 USC § 103

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-8, 10-15 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam et al [5,640,489; 102(e) date of at least 7/2/91] in view of Fodor et al [Science 251:

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767 (1991)] and applicants' disclosure of the prior art teachings.

With respect to independent claims 1 and 10: Lam et al teach the synthesis of random bio-oligomers (which reads on diverse polymers, see abstract) which may be peptides or oligonucleotides or a peptide oligonucleotide chimera (col. 5, lines 8-17). Lam et al teach the synthesis of the oligomers using the split and combine method whereby individual beads are used to synthesize one polymer per bead (figure 1). Lam et al teach synthesizing arrays of polymers using different protocols in order to compare the results of the synthetic process on the array produced. Lam et al also teach separately cleaving the collections of polymers from the support beads to form separate mixtures and measuring the components present via a property (UV absorbance in this instance) in order to examine the products produced using similar synthesis protocols. Lam et al specifically note that the incorporation of individual components such as valine are different between the methods employed which reads on measuring a "property" (the composition) of the mixture of unbound polymers as an indicator of the efficiency of the synthesizing step (see figure 3 and col. 34, line 60 - col. 35, line 55). In that the array of polymers produced in one method is compared to the array produced in the second method one array reads on a reference array.

With respect to the dependent claims, Lam et al specifically recites the oligomers of the array can be oligonucleotides as required in claims 8 and 11 (col. 5, lines 8-17). Lam et al teach that the use of cleavable linkers, as required by claim 13, are well known in the art (col. 16, lines 10-40). In that the peptides exemplified by Lam et al were detected by their absorbance at 215 nm (see figure 3 left axis) they clearly are comprised of a detectable label as defined by applicant

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on page 12 of the specification and required in claim 14. In that the 215 nm absorbance by the exemplified peptides in Figure 3 is due to the amide bonds of the backbone the polymers comprise a label other than a monomer unit as required by claim 39. [That the absorbance at 215 nm is due to the amide backbone is well known in the art. However, the examiner has attached pages 161-162 of *Spectrophotometric identification of Organic Compounds (2nd ed, 1967)* for applicants convenience which clearly evidences this assertion]. Additionally, it is noted that the indole ring of tryptophan can serve as a detectable label at 280 nm (see Lam et al col. 33, lines 55-57) and that the indole ring itself does not comprise a monomer. Therefore, Lam et al additionally reads on instant claim 39. In that the backbone amide chromophore comprises a single isomer and alternatively the indole of tryptophan comprises a single isomer (which is fluorescent) Lam et al reads on claims 14, 15 and 38. In that each of the peptides in the exemplified arrays contain a tryptophan they comprise a single isomer as required by claim 2. In addition, since different peptides with different compositions and masses are present, they are heterogeneous by "size." In that Lam et al teach the use of reverse phase HPLC to monitor the composition of the oligomer mixtures cleaved from the array, Lam et al render obvious the use of other well-known HPLC methods, which in view of applicants' disclosure of prior art teachings are notoriously well known and established in the art (see pages 38 and 39 of the specification). In addition, the analyses of mixtures of materials by gel electrophoresis as required in claim 5, especially the analysis of peptides and nucleotides is notoriously well known in the art as clearly evidenced by applicants' reliance on standard texts, laboratory manuals and manufacturers' literature, see page 38 and 39 of the specification.

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Lam et al do not teach the formation of arrays on planer surfaces, where each member of the polymer set occupies a different region of the substrate.

Fodor et al teach the synthesis of polymer arrays on planar substrates where each member of the polymer array occupies a different region of the substrate.

It would have been *prima facia* obvious to one of ordinary skill in the art at the time the invention was made to monitor the synthesis of polymer arrays synthesized on a planer support as taught by Fodor using a method of analysis as taught by Lam et al, because Lam et al teach the desirability of monitoring polymer array synthesis in order to compare the methods utilized in the synthetic process (see example 7 "*Comparison of the claimed method with the conventional method of peptide synthesis*" starting in column 7 at line 60) which is applicable to arrays synthesized on any support(s). One of ordinary skill in the art would have been motivated to do so in order to compare array synthesis protocols and optimize array synthesis (which is desirable whether the array has been prepared on a planar support or spherical supports, segmental supports, fiber supports... as are each are known in the art) as taught by Lam et al (*loc cit.*). One ordinary skill in the art would reasonably have expected to be successful because the basic method of preparing an array of oligomers on supports, cleaving them to form a mixture of oligomers and analyzing them had already been conducted by Lam et al. One of ordinary skill in the art would also have reasonably expected the use of gel electrophoresis, and HPLC chromatography to be successful because these are notoriously well known methods of analysis which have been applied to oligomeric compounds such as peptides and nucleotides.

16. *Applicants' arguments filed 9/20/99 have been fully considered but they are not*

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persuasive.

Applicants' assert that Lam et al provides no motivation that it may be modified in the manner suggested by the examiner and that lame is directed to the use of resin beads and not to planer surfaces. Applicants assert that Lam provides no guidance for creating diverse polymers on a planer surface. Applicants conclude from the aforementioned arguments that Lam provides no reasonable expectation of success in using planer supports.

Applicants' arguments have been considered but are not found persuasive. The assertion that Lam et al provide no motivation to be modified to use planer supports is not found persuasive because Lam et al clearly set forth the desirability of comparing synthesis protocols (i.e., determining the synthesis efficiency etc...) Applicants' next assertion that Lam is limited to resin beads and not to planer surfaces is also not persuasive as the chemistry set forth Lam et al and required by the rejection of record would not be affected by required would not be affected by the shape of the synthesis support. Moreover, the argument fails to consider the teaching of Fodor et al. Applicants last assertion Lam et al provide no guidance for creating diverse polymers on a planer surface is not persuasive as it does not take into account the teachings of Fodor et al which were cited for this purpose. Therefore, the rejection is maintained for the reasons above and for the reasons of record in paper number 23.

17. Claims 1-8, 10-15 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam et al [5,640,489; 102(e) date of at least 7/2/91] in view of Holmes [US 5,679,773] and applicants' disclosure of the prior art teachings.

See the teachings of Lam et al and applicants' disclosure of the prior art teaching as

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applied to claims 1-8, 10-15 and 37-39 under 35 USC 103(a) as being unpatentable over Lam et al in view of Fodor and applicants disclosure of the teachings of the prior art, *supra*.

Holmes et al teach the synthesis of polymer arrays on planar substrates where each member of the polymer array occupies a different region of the substrate and the desirability of determining the fidelity of synthesis of such arrays (column 19, lines 33-58).

It would have been *prima facia* obvious to one of ordinary skill in the art at the time the invention was made to monitor the synthesis of polymer arrays synthesized on a planer support as taught by Holmes using a method of analysis as taught by Lam et al, because Lam et al teach the desirability of monitoring polymer array synthesis in order to compare the methods utilized in the synthetic process (see example 7 "*Comparison of the claimed method with the conventional method of peptide synthesis*" starting in column 7 at line 60) which analyze mixtures of polymers cleaved from the support and Holmes teaches the desirability of determining the fidelity of array synthesis on planar supports by cleaving the polymers from the support. One of ordinary skill in the art would have been motivated to do so in order to compare array synthesis protocols and the resulting fidelity of array synthesis as suggested by Lam et al and Holmes. One ordinary skill in the art would reasonably have expected to be successful because the basic method of preparing an array of oligomers on supports, cleaving them to form a mixture of oligomers and analyzing them had already been conducted by Lam et al. One of ordinary skill in the art would also have reasonably expected the use of gel electrophoresis, and HPLC chromatography to be successful because these are notoriously well known methods of analysis which have been applied to oligomeric compounds such as peptides and nucleotides.

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18. *Applicants' arguments filed 9/20/99 have been fully considered but they are not persuasive.*

Applicants assert that Lam et al provides no motivation that it may be modified in the manner suggested by the examiner and that lame is directed to the use of resin beads and not to planer surfaces. Applicants assert that Lam provides no guidance for creating diverse polymers on a planer surface. Applicants conclude from the aforementioned arguments that Lam provides no reasonable expectation of success in using planer supports.

Applicants' arguments have been considered but are not found persuasive. The assertion that Lam et al provide no motivation to be modified to use planer supports is not found persuasive because Lam et al clearly set forth the desirability of comparing synthesis protocols (i.e., determining the synthesis efficiency etc...) and Holmes sets forth the desirability of monitoring synthesis fidelity. Applicants' next assertion that Lam et al are limited to resin beads and not to planer surfaces is also not persuasive as the chemistry set forth Lam et al, required by the rejection of record, would not be affected by the shape of the synthesis support. Moreover, the argument fails to consider the teachings of Holmes. Applicants last assertion Lam et al provide no guidance for creating diverse polymers on a planer surface is not persuasive as it does not take into account the teachings of Holmes which were cited for this purpose. Therefore, the rejection is maintained for the reasons above and for the reasons of record in paper number 23.

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New Ground of Rejection

Claim Rejections - 35 USC § 112

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 2 has been amended to recite that the polymers are a single optical isomer. Applicants have failed to indicate where support for the amendment can be found in the disclosure as originally filed. Applicants can overcome this rejection by indicating where support can be found in the disclosures as originally filed.

21. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

22. Claims 2 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

23. Claim 2 recites the polymer comprises a single optical isomer. This is vague and

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indefinite because it is unclear if molecules which are achiral are intended to be included or excluded by the instant claim language. Therefore, it is not possible to determine the metes and bounds of the invention as claimed.

24. Claim 15 recites that the label is a single optical isomer. This is vague and indefinite because it is not possible to determine if achiral labels (labels with no chiral centers) are to be included or excluded in the invention as claimed. It is noted that applicants refer to and utilize the concept of “mono-isomeric” which they define as meaning only one optical isomer is present (page 19, lines 1-7). However, at page 29 applicants refer to mono-isomeric labels as not giving rise to multiple species when coupled to a polymer, which would include achiral molecules. Moreover, the disclosure on page 29 sets forth many molecules as mono-isomeric which are achiral. Therefore, is not possible to determine what are metes and bounds of a label which is “a single optical isomer” as it appears to include molecules which are achiral (having no chiral centers) yet they must be optically active if they are to be a single optical isomer.

Conclusion

25. Applicants’ amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph W. Ricigliano Ph. D. whose telephone number is (703) 308-9346. The examiner can normally be reached on Monday through Thursday from 7:30 A.M. to 5:00 P.M. and alternate Fridays from 7:30 A.M. to 5:00 P.M.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703) 308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Adams, can be reached at (703) 308-0570.

**BENNETT CELSA
PRIMARY EXAMINER**

Joseph W. Ricigliano Ph. D.

Bennett Celsa 11/30/91